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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,137	03/23/2005	Michael Ziegler	82291	1505

23685 7590 09/01/2009

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EXAMINER	
FUJITA, KATRINA R	
ART UNIT	PAPER NUMBER
2624	

MAIL DATE	DELIVERY MODE
09/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,137	ZIEGLER, MICHAEL	
	Examiner	Art Unit	
	KATRINA FUJITA	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,22-30 and 32-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,22-30 and 32-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 05, 2009 has been entered.

Response to Amendment

2. This Office Action is responsive to Applicant's remarks received on August 05, 2009. Claims 1-20, 22-30 and 32-39 remain pending.

Claim Objections

3. The previous claim objections have been withdrawn in light of Applicant's amendment.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 11, 12, 16, 18, 25, 29, 30, 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al. (US 5,763,265) and Rowe et al. (US 7,126,682).

Regarding **claim 1**, Itsuzaki et al. discloses a method for analyzing body fluids ("specimen testing method" at col. 1, line 5), characterized in that an image recording device (figure 7, numeral 22) is used to produce at least one image of the body fluid ("image of separated blood" at col. 4, line 35) located in a container (figure 7, numeral 1) that is analyzed by means of image processing software (figure 7, numeral 10-13 imply software), that detects solid particles in the serum and/or plasma ("clot components" at col. 3, line 5) using color values ("color digital image data" at col. 4, line 35).

Itsuzaki et al. does not disclose that in order to detect solid particles in the serum and/or plasma, the region corresponding to the serum is compared with stored color values of reference samples and classified as "clear" or "not clear".

Rowe et al. teaches a method in the same field of endeavor of biological sample analysis ("perform spectroscopic determinations on biological media" at col. 3, line 58) characterized in that in order to detect solid particles ("quantity of an analyte" at col. 3, line 59) in the sample ("fluids measured either in-vivo or in-vitro derived from humans" at col. 3, line 65), the region corresponding to the sample is compared with stored color values or reference samples and classified ("checking for sample quality and consistency with a known class of samples" at col. 3, line 61).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the sample quality comparison of Rowe et al. in the system of Itsuzaki et al. to help ensure that only samples of sufficient quality are processed such that relevant diagnostic information can be obtained.

The Itsuzaki et al. and Rowe et al. does not explicitly state that the samples are classified as "clear" or "not clear".

However, the method does check for sample quality and clarity is a measure of sample quality.

Therefore, it would have been obvious at the time the invention was made to one of ordinary skill in the art to classify the samples of the Itsuzaki et al. and Rowe et al. combination based on clarity as another way of quantifying the quality of the sample such that only samples of sufficient quality are processed.

Regarding **claim 11**, Itsuzaki et al. discloses a method characterized in that a color image of the body fluid and of the container is produced ("outputting the image as color digital image data" at col. 4, line 35).

Regarding **claim 12**, Itsuzaki et al. discloses the elements of claim 11 as described above.

Itsuzaki et al. does not explicitly disclose that the color image of the body fluid and/or container are/is converted automatically into a gray value image.

However, Itsuzaki et al. does show that the sample analysis can be done using grey-level images in another embodiment ("visual sensor for taking an image of the separated blood 1 and outputting the image as monochromatic image data" at col. 3, line 10; figure 1). Furthermore, it is well-known in the art to convert color images to grey-level images prior to further analysis as a form of image segmentation.

Therefore it would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize a grey-level conversion of the color data of the Itsuzaki et al. and Rowe et al. combination to maximize the contrast between the relevant image information and background information.

Regarding **claim 16**, Itsuzaki et al. discloses a method characterized in that for the purpose of evaluating the image of a body fluid, a number of perpendicular and/or horizontal lines are laid in the image of the body fluid ("projection data row obtained by adding image data in every one of all horizontal lines in the boundary detection region" at col. 3, line 49), the color values and/or brightness values of the pixels lying on these lines are detected ("positions of peak differential values may be obtained" at col. 3, line

52, which correspond to image data values with particular intensities), changes in color value and/or brightness value are determined (the peak values indicate transition points), and a background region and/or upper edge of the body fluid are determined (“upper boundary 5” at col. 3, line 48).

Regarding **claim 18**, Itsuzaki et al. discloses a method characterized in that in order to identify the separating means and/or the blood clot in a centrifuged sample of body fluid (figure 7, numeral 1), each pixel row of the image is scanned (“projection data row obtained by adding image data in every one of all horizontal lines in the boundary detection region" at col. 3, line 49), and the transition from dark color or brightness values to brighter color or brightness values is detected (“positions of peak differential values may be obtained" at col. 3, line 52, which correspond to image data values with particular intensities; the peak values indicate transition points) and defined as phase boundary between blood clot and a separating means or between the separating means and serum (“detects the upper boundary position 5 of serum components" at col. 3, line 33; "lower boundary position 6 of serum components detected" at col. 3, line 54).

Itsuzaki et al. does not disclose that the image is scanned from bottom to top.

However, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to scan the image from bottom to top as one of ordinary skill in the art would have expected Applicant’s invention to perform equally well with either the scan direction of the Itsuzaki et al. and Rowe et al. combination or the claimed bottom to top scan direction because both scan directions perform the same function of detecting image intensities such that transition points between sample components can be found.

Regarding **claim 25**, the Itsuzaki et al. and Rowe et al. combination discloses a method characterized in that a color value is determined for each pixel for the purpose of color analysis of the serum ("image data included in the range of a preliminarily detected detection serum color from the three attribute data" Itsuzaki et al. at col. 4, line 42), is compared with stored color values of classified reference samples ("consistency with a known class of samples" Rowe et al. at col. 3, line 61), and is classified as "good" or "not good" ("checking for sample quality" Rowe et al. at col. 3, line 61, which implies a determination of whether the sample is good or not).

Regarding **claim 29**, the Itsuzaki et al. and Rowe et al. combination discloses a method characterized in that images of known samples are produced, classified into classes and stored in data file/files in order to produce reference data ("checking for sample quality and consistency with a known class of samples" Rowe et al. at col. 3, line 61).

Regarding **claim 30**, the Itsuzaki et al. and Rowe et al. combination discloses a method characterized in that color features are extracted at least once for all the images of the individual classes ("image data included in the range of a preliminarily detected detection serum color from the three attribute data" Itsuzaki et al. at col. 4, line 42; "known class of samples" Rowe et al. at col. 3, line 61).

Regarding **claim 32**, the Itsuzaki et al. and Rowe et al. combination does not explicitly disclose a computer programmed for carrying out the method of claim 1.

However, it is well-known to utilize computers for purposes of image processing and therefore would have been obvious at the time the invention was made such that the data can be efficiently processed for further understanding of the results.

Regarding **claim 33**, the Itsuzaki et al. and Rowe et al. combination discloses an apparatus for analyzing body fluids ("specimen testing method and its apparatus" at col. 1, line 5), characterized in that an image recording device is provided (figure 7, numeral 22) and is connected to an electronic image evaluation apparatus (figure 7, numeral 10-13 imply software), said apparatus including at least one computer (see claim 32 above).

Regarding **claim 34**, the Itsuzaki et al. and Rowe et al. combination does not explicitly disclose a digital storage medium having electronically readable control signals that can cooperate with a programmed computer system for carrying out the method of claim 1.

However, it is well-known to utilize digital storage mediums for purposes of image processing and therefore would have been obvious at the time the invention was made such that the data can be efficiently processed for further understanding of the results.

Regarding **claim 35**, the Itsuzaki et al. and Rowe et al. combination discloses a digital storage medium (see claim 34 above) that has control software (figure 7, numeral 10-13 imply software) for controlling an apparatus for analyzing body fluids ("specimen testing method and its apparatus" at col. 1, line 5), said apparatus being characterized in that an image recording device is provided (figure 7, numeral 22) and is connected to

an electronic image evaluation apparatus (figure 7, numeral 10-13 imply software; see claim 32 above).

Regarding **claim 36**, the Itsuzaki et al. and Rowe et al. combination discloses a digital storage medium that has image processing software for analyzing images (figure 7, numeral 10-13 imply software).

Regarding **claim 37**, the Itsuzaki et al. and Rowe et al. combination does not explicitly disclose a computer readable storage medium for carrying out the method of claim 1.

However, it is well-known to utilize computer readable storage mediums for purposes of image processing and therefore would have been obvious at the time the invention was made such that the data can be efficiently processed for further understanding of the results.

Regarding **claim 38**, the Itsuzaki et al. and Rowe et al. combination discloses a computer readable storage medium (see claim 37 above) that has control software (figure 7, numeral 10-13 imply software) for controlling an apparatus for analyzing body fluids ("specimen testing method and its apparatus" at col. 1, line 5), said apparatus being characterized in that an image recording device is provided (figure 7, numeral 22) and is connected to an electronic image evaluation apparatus (figure 7, numeral 10-13 imply software; see claim 32 above).

Regarding **claim 39**, the Itsuzaki et al. and Rowe et al. combination discloses a computer readable storage medium that has image processing software for analyzing images (figure 7, numeral 10-13 imply software).

6. Claims 2-6, 13, 14, 17, 19 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al. and Rowe et al. as applied to claims 1, 11, 12 and 16 above, and further in view of Watson et al.

Regarding **claim 2**, the Itsuzaki et al. and Rowe et al. combination discloses the elements of claim 1 as described above.

The Itsuzaki et al. and Rowe et al. combination does not disclose that firstly the type and size of the container are determined automatically.

Watson et al. discloses a method characterized in that firstly the type and size of the container are determined automatically ("captures the shape and colour of the cap" at page 20, line 13; "This allows the system to positively identify tubes 14 which have two colours on the top of the cap" at page 20, line 15).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the container detection of Watson et al. for the samples of the Itsuzaki et al. and Rowe et al. combination to allow sample analysis to be conducted for more than one container type.

Regarding **claim 3**, Watson et al. discloses a method characterized in that an image of the container is produced with the aid of the image recording device ("digital camera 22 also captures the dimensions of the tube" at page 20, line 17) and is compared with the aid of evaluation software with stored image files and/or dimensions of known containers ("Along with information in the windows for capturing characteristics of each type of tubes 14, in the memory are also stored information

relating to corresponding brand, type, volume, gel content, etc. Therefore when a match or close match is determined, the computer can identify the type of tube" at page 23, line 21).

Regarding **claim 4**, Watson et al. discloses a method characterized in that caps of the tubes holding the body fluid are compared ("captures the shape and colour of the cap" at page 20, line 13; "This allows the system to positively identify tubes 14 which have two colours on the top of the cap" at page 20, line 15), and the type of tube and height of tube are determined thereby ("digital camera 22 also captures the dimensions of the tube" at page 20, line 17).

Regarding **claim 5**, the Itsuzaki et al., Rowe et al. and Watson et al. combination discloses the elements of claim 2 as described above.

The Itsuzaki et al., Rowe et al. and Watson et al. combination does not disclose that after determination of the type and size of the container, the container is moved automatically in such a way that as complete an image as possible of the body fluid can be produced by means of the image recording device.

Watson et al. discloses a method characterized in that after determination of the type and size of the container, the container is moved automatically in such a way that as complete an image as possible of the body fluid can be produced by means of the image recording device ("In order that the specimen is correctly captured by the digital camera 22, a controller (not shown), upon receiving a signal from the reader 20, rotates a pair of gripper 146 holding the tube 14 by a predetermined angle so that the camera

22 can capture images of the sample through a portion or window of the tube 14 not obscured by the label 88 and the tube manufacture's label" at page 20, line 19).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the container controller of Watson et al. to handle the samples of the Itsuzaki et al., Rowe et al. and Watson et al. combination to ensure that "the specimen is correctly captured by the digital camera 22" (Watson et al. at page 20, line 19).

Regarding **claim 6**, the Itsuzaki et al. and Rowe et al. combination discloses the elements of claim 1 as described above.

The Itsuzaki et al. and Rowe et al. combination does not disclose that the container is moved automatically such that as complete an image as possible of the body fluid can be produced.

Watson et al. discloses a method characterized in that the container is moved automatically such that as complete an image as possible of the body fluid can be produced ("a controller (not shown), upon receiving a signal from the reader 20, rotates a pair of gripper 146 holding the tube 14 by a predetermined angle so that the camera 22 can capture images of the sample through a portion or window of the tube 14 not obscured by the label 88 and the tube manufacture's label" at page 20, line 20).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the container controller of Watson et al. to handle the samples of the Itsuzaki et al. and Rowe et al. combination to ensure that "the specimen is correctly captured by the digital camera 22" (Watson et al. at page 20, line 19).

Regarding **claim 13**, the Itsuzaki et al. and Rowe et al. combination discloses a method characterized in that a number of vertical lines are laid in the image of the container ("position detecting lines 16a to 16n for detecting the concentration change points are provided in the vertical direction" at col. 3, line 38), the color values and/or brightness values of the pixels lying on these lines are detected (the image data is evaluated according to intensities), and changes in color value and/or brightness value are determined ("positions 17a to 17n at peaks of differential values are detected" at col. 3, line 44, which correspond to image data values with particular intensities).

The Itsuzaki et al. and Rowe et al. combination does not disclose detecting the type and size of the container and comparing changes in color value and/or brightness with the data of known containers.

Watson et al. discloses a method characterized in that for the purpose of detecting the type and size of the container, changes in color value and/or brightness value are determined and compared with the data of known containers ("Subtract A1 of current image from A1 of reference using LUT" at page 22, line 18; color changes over the pixels of the sub-images are observed by this difference).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the container detection of Watson et al. for the samples of the Itsuzaki et al. and Rowe et al. combination to allow sample analysis to be conducted for more than one container type.

Regarding **claim 14**, the Itsuzaki et al., Rowe et al. and Watson et al. combination discloses a method characterized in that a handling apparatus (Watson et

al. at figure 5, numeral 46) is controlled with the aid of the data determined for the container ("Information concerning the placement of tubes 14, 15 in specific destination racks is also sent to the computerised laboratory information management system" Watson et al. at page 25, line 3).

Regarding **claim 17**, the Itsuzaki et al. and Rowe et al. combination discloses the elements of claim 16 as described above.

The Itsuzaki et al. and Rowe et al. combination does not disclose that the background region is removed from the image computationally.

Watson et al. teaches a method for analyzing body fluids ("analyzer is arranged to detect the level of the sample" at page 6, line 23) characterized in that the background region is removed from the image computationally ("Blank out unused areas (cap area, bottom radius) using the physical properties of the tube" at page 23, line 1).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the image blanking of Watson et al. on the image data of the Itsuzaki et al. and Rowe et al. combination to eliminate unnecessary image data during analysis of the container contents.

Regarding **claim 19,** the Itsuzaki et al. and Rowe et al. combination discloses the elements of claim 18 as described above.

The Itsuzaki et al. and Rowe et al. combination does not disclose that the image region determined for the separating means and/or the blood clot is removed from the image computationally.

Watson et al. teaches a method for analyzing body fluids ("analyzer is arranged to detect the level of the sample" at page 6, line 23) characterized in that the background region is removed from the image computationally ("Blank out unused areas (cap area, bottom radius) using the physical properties of the tube" at page 23, line 1).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the image blanking of Watson et al. on the separating means and blood clot image data of the Itsuzaki et al. and Rowe et al. combination to eliminate unnecessary image data during analysis of the container contents.

Regarding **claim 28**, the Itsuzaki et al. and Rowe et al. combination discloses the elements of claim 1 as described above.

The Itsuzaki et al. and Rowe et al. combination does not disclose a handling apparatus is controlled with the aid of a classification determined for the serum.

Watson et al. teaches a method characterized in that a handling apparatus is controlled with the aid of a classification determined for the serum ("a controller (not shown), upon receiving a signal from the reader 20, rotates a pair of gripper 146 holding the tube 14 by a predetermined angle so that the camera 22 can capture images of the sample through a portion or window of the tube 14 not obscured by the label 88 and the tube manufacture's label" at page 20, line 20).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the container controller of Watson et al. to handle the samples of

the Itsuzaki et al. and Rowe et al. combination to ensure that “the specimen is correctly captured by the digital camera 22” (Watson et al. at page 20, line 19).

The Itsuzaki et al., Rowe et al. and Watson et al. combination does not disclose that “good” and/or “clear” samples are passed for further analysis, and “not good” and/or “not clear” samples are rejected.

However, it is well-known in the art to reject samples of insufficient quality for further processing and therefore would have been obvious at the time the invention was made to accept “good” and/or "clear" samples and reject "not good" and/or "not clear" samples to avoid processing a sample that would not produce an accurate determination of its contents based on the fact that its quality is insufficient.

7. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al., Rowe et al. and Watson et al. as applied to claim 6 above, and further in view of Michelotti et al. (US 5,755,335).

Regarding **claim 7**, the Itsuzaki et al., Rowe et al. and Watson et al. combination discloses the elements of claim 6 as described above.

The Itsuzaki et al., Rowe et al. and Watson et al. combination does not disclose that a scanner and/or image evaluation software are provided for detecting an inscription placed on the container, a label and/or a cover, and in that the scanner detects a bar code and the container is moved automatically such that the cover is situated on the side of the container averted from the image recording device.

Watson et al. discloses a method characterized in that a scanner and/or image evaluation software are provided for detecting an inscription placed on the container ("controller is programmed to image predefined windows" at page 21, line 10), a label and/or a cover ("label 88 and the tube manufacture's label" at page 20, line 23), and in that the scanner detects a bar code (figure 8A, numeral 20) and the container is moved automatically such that the cover is situated on the side of the container averted from the image recording device ("In order that the specimen is correctly captured by the digital camera 22, a controller (not shown), upon receiving a signal from the reader 20, rotates a pair of gripper 146 holding the tube 14 by a predetermined angle so that the camera 22 can capture images of the sample through a portion or window of the tube 14 not obscured by the label 88 and the tube manufacture's label" at page 20, line 19).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the container controller of Watson et al. to handle the samples of the Itsuzaki et al. and Rowe et al. combination to ensure that "the specimen is correctly captured by the digital camera 22" (Watson et al. at page 20, line 19) and to ensure the correct specimen is captured.

The Itsuzaki et al., Rowe et al. and Watson et al. combination does not disclose detecting the edges of the cover.

Michelotti et al. teaches a method in the same field of endeavor of label inspection ("inspection of labels thereon" at col. 1, line 11) that detects the edges of the

cover ("label edge detection system and rotationally orienting the container 12 based upon the detected label edge" at col. 8, line 50).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the edge detection of Michelotti et al. to orient the containers of the Itsuzaki et al., Rowe et al. and Watson et al. combination to ensure that the container may be consistently imaged by the camera.

Regarding **claim 8**, the Itsuzaki et al, Rowe et al., Watson et al. and Michelotti et al. combination discloses the elements of claim 7 as described above.

The Itsuzaki et al, Rowe et al., Watson et al. and Michelotti et al. combination does not disclose following an optical blanking out of a cover the container is covered on the side averted from the image recording device.

However, Watson et al. does disclose optical blanking out image data (“Blank out unused areas (cap area, bottom radius) using the physical properties of the tube” at page 23, line 1).

Therefore, it would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the image blanking of Watson et al. on the label of the Itsuzaki et al, Rowe et al., Watson et al. and Michelotti et al. combination to eliminate unnecessary image data during analysis of the container contents.

Regarding **claim 9**, the Itsuzaki et al, Rowe et al., Watson et al. and Michelotti et al. combination discloses the elements of claim 8 as described above.

The Itsuzaki et al, Rowe et al., Watson et al. and Michelotti et al. combination does not explicitly disclose that 15 to 50%, preferably 20 to 25%, of the outer surface of the container is covered.

However, Watson et al. discloses test tubes with labels that cover 20 to 25% of the container (see figures 2, 5 and 8A, numeral 14).

Therefore, as it has already been established that it would have been obvious at the time the invention was made to one of ordinary skill in the art to blank out the labels of the Itsuzaki et al, Rowe et al., Watson et al. and Michelotti et al. combination, 15 to 50%, preferably 20 to 25%, of the outer surface of the container is covered as a result.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al. and Rowe et al. as applied to claim 1 above, and further in view of Watson et al. and Schemmel et al (US 6,175,646).

The Itsuzaki et al. and Rowe et al. combination discloses a method characterized in that the image recording device (figure 7, numeral 22) is used to produce an image of the body fluid ("image of separated blood" at col. 4, line 35) in a first container (figure 7, numeral 1).

The Itsuzaki et al. and Rowe et al. combination does not explicitly disclose an image of a second subsequent container for the purpose of determining the type and size of the second container.

Watson et al. discloses a method characterized in that the image recording device is used to produce an image of the body fluid in a first container (image of figure

1, numeral 14) and an image of a subsequent second container (subsequent tube image) for the purpose of determining the type and size of the second container (determining what tube type and its specimen volume).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the container detection of Watson et al. for the samples of the Itsuzaki et al. and Rowe et al. combination to allow sample analysis to be conducted for more than one container type.

The Itsuzaki et al., Rowe et al. and Watson et al. combination does not disclose that both images are produced simultaneously.

Schemmel et al. teaches a method in the same field of endeavor of object inspection, characterized in that multiple images are produced simultaneously (“captures one or more die images simultaneously” at col. 1, line 67) prior to comparison to reference images ("compared to silicon dies images" at col. 2, line 3).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the simultaneous imaging of Schemmel to produce the container images of the Itsuzaki et al., Rowe et al. and Watson et al. combination to be able to process more units at once (see Schemmel at col. 5, line 67- col. 6, line 7).

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al. and Rowe et al. as applied to claim 1 above, and further in view of Minden (US 6,342,143).

The Itsuzaki et al. and Rowe et al. combination discloses the elements of claim 1 as described above.

The Itsuzaki et al. and Rowe et al. combination does not disclose one or more detail images that are combined by means of the image processing software to form an overall image.

Minden teaches a method in the same field of endeavor of biological sample analysis ("imager is provided for providing images of samples" at col. 2, line 39) characterized in that one or more detail images are produced (“tiled images” at col. 7, line 5) that are combined by means of the image processing software to form an overall image (“computationally assembled to create one complete image" at col. 7, line 10; “CCD camera is connected to computer” at col. 4, line 65).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the composite image assembly of Minden to produce detailed images of the sample of the Itsuzaki et al. and Rowe et al. combination such that the user can be presented with one image that highlights the intricacies of the layers so that a more accurate result can be obtained.

10. Claims 20, 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al. and Rowe et al. as applied to claim 1 above, and further in view of Hsu (US 5,640,468).

Regarding **claim 20**, the Itsuzaki et al. and Rowe et al. combination discloses a method characterized in that in order to identify blood serum/plasma and/or separating

means and/or blood clot, regions of pixels with similar color values are determined (“positions of peak differential values may be obtained" at col. 3, line 52, which correspond to image data values with particular intensities; the peak values indicate transition points), and the resulting regions are defined as serum, separating means and/or blood clot (“detects the upper boundary position 5 of serum components" at col. 3, line 33; "lower boundary position 6 of serum components detected" at col. 3, line 54).

The Itsuzaki et al. and Rowe et al. combination does not disclose a region-grow method.

Hsu teaches a method in the same field of endeavor of object recognition (“object/feature extraction by generating uniform regions” at col. 1, line 7) characterized in that by means of a region-grow method (“region-growing method” at col. 12, line 44), regions of pixels with similar color values are determined (“segmentation yields a segmentation map that corresponds to a visual segmentation of the color map” at col. 12, line 47).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the region-growing of Hsu to segment the image data of the Itsuzaki et al. and Rowe et al. combination to "provide a method for segmenting an image with minimal mathematical computation” at col. 3, line 37).

Regarding **claim 24**, Itsuzaki et al. discloses a method characterized in that in order to determine the volume of the blood serum, upper and lower limits of the serum region are determined automatically (“detects the upper boundary position 5 of serum components" at col. 3, line 33; "lower boundary position 6 of serum components

detected" at col. 3, line 54), and the volume is calculated automatically with the aid of the diameter of the container ("serum component amount N is calculated from the diameter M of a test tube" at col. 4, line 8).

Regarding **claim 27**, the Itsuzaki et al., Rowe et al. and Hsu et al. combination discloses a method characterized in that the serum is classified overall as "good" when the majority of the pixels are classified as "good", and in that the serum is classified overall as "not good" when the majority of the pixels are classified as "not good" (as established, the quality of the sample is checked by comparing the current sample to reference samples. As such, it would only follow that a majority of pixels classified in either category would indicate an overall sample quality).

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al., and Rowe et al. as applied to claim 1 above, and further in view of Yamazaki et al. (US 5,880,835).

The Itsuzaki et al. and Rowe et al. combination discloses the elements of claim 20 as described above.

The Itsuzaki et al. and Rowe et al. combination does not disclose that the particles are classified in terms of shapes or colors.

Yamazaki et al. teaches a method in the same field of endeavor of biological sample analysis ("apparatus for investigating urinary sediments in urine, or blood cells in blood" at col. 1, line 15) characterized in that particles are classified in terms of

shapes or colors ("classifies each particle into corresponding shape classes" at col. 19, line 37).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the shape classification of Yamazaki et al. to classify the image data of the Itsuzaki et al. and Rowe et al. combination such that "particles can be counted accurately and exact particle concentrations can be obtained" at col. 19, line 53).

12. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al., Rowe et al. and Hsu as applied to claim 20 above, and further in view of Watson et al.

The Itsuzaki et al., Rowe et al. and Hsu combination discloses the elements of claim 20 as described above.

The Itsuzaki et al. and Hsu combination does not disclose that the image region determined for the separating means and/or the blood clot is removed from the image computationally.

Watson et al. teaches a method for analyzing body fluids (“analyzer is arranged to detect the level of the sample” at page 6, line 23) characterized in that the background region is removed from the image computationally (“Blank out unused areas (cap area, bottom radius) using the physical properties of the tube” at page 23, line 1).

It would have been obvious at the time the invention was made to one of ordinary skill in the art to utilize the image blanking of Watson et al. on the separating means and blood clot image data of the Itsuzaki et al., Rowe et al. and Hsu combination to eliminate unnecessary image data during analysis of the container contents.

13. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Itsuzaki et al., and Rowe et al. as applied to claim 25 above, and further in view of Bills (US 6,366,319).

The Itsuzaki et al. and Rowe et al. combination discloses a method characterized in that a comparison is undertaken in a color space ("hue information, H, luminance information V, and saturation information, C" Itsuzaki et al. at col. 4, line 40).

The Itsuzaki et al. and Rowe et al. combination does not disclose that the color space is a “CIE lab” space.

However, it is common knowledge in the art to convert from a color space to CIE lab space (“convert the interpolated CYW color planes to CIELAB color space” Bills at col. 14, line 56).

Therefore, it would have been obvious at the time the invention was made to one of ordinary skill in the art to convert the color space of the Itsuzaki et al. and Rowe et al. combination to conduct the comparison as an "advantage to using CIELAB color space is that the color gamut or saturation can be limited to reduce color aliasing or color noise" at col. 15, line 1).

Response to Arguments

Summary of Remarks (@ response page labeled 11): The Rowe reference does not specify the quality criteria and therefore does not disclose the need to "detect the quality of the samples in question only by the criteria "clear" or "not clear"."

Examiner's Response: The Examiner has not asserted that the Rowe reference specified the quality criteria. As outlined in the rejection in the previous Office Action, clarity of the sample is a measure of the quality of the sample, and therefore obvious at the time the invention was made to one of ordinary skill in the art as another way of quantifying the quality of the sample such that only samples of sufficient quality are processed. Furthermore, the claim does not require the quality of the samples to be determined *only* by a clarity criterion.

Summary of Remarks (@ response pages labeled 12-16): The Watson, Michelotti, Schemmel, Minden, Hsu, Yamazaki and Bills references do not disclose how to measure the quality of samples.

Examiner's Response: The Examiner has not utilized any of these references for support of the sample quality limitation (clarity). Therefore, this argument is moot.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATRINA FUJITA whose telephone number is (571)270-1574. The examiner can normally be reached on M-Th 8-5:30pm, F 8-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Werner can be reached on (571) 272-7401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katrina Fujita/
Examiner, Art Unit 2624

/Brian P. Werner/
Supervisory Patent Examiner, Art Unit 2624